

**Fertility Institute
of
Fort Lauderdale**

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Infertility, Assisted Reproduction (IVF), Gynecologic Endoscopy, Laser and Microsurgery JAN -5 P2:30

Eliezer J. Livnat, M.D., F.A.C.O.G., Medical Director
Michael Matilsky, Ph.D., HCLD, IVF Laboratory Director

December 23, 1999
Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket # 97N-4845 - Suitability Determination
for Donors of Human Cellular and Tissue-
Based Products.

To Whom It May Concern:

We support SART and ASRM in
objection to the newly proposed rules
affecting donor egg IVF cycles. Please
reconsider according to the enclosed fact
sheet.

97N 4845

DR. MOSHE MATILSKY, Ph.D.
INFERTILITY UNIT

Sincerely,

M. B. Matilsky

C395
Dr. Livnat

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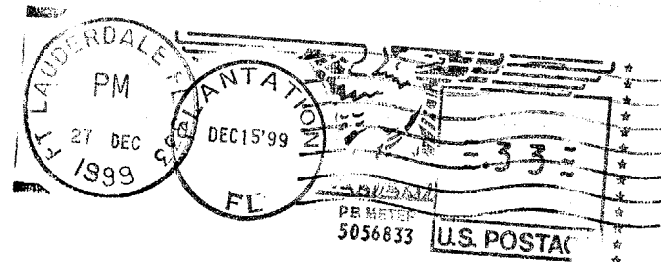
Fact Sheet Re: Quarantining of Donor Embryos

1. There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. HIV or other infectious diseases are not passed by IVF-ET. No specific papers claiming this have been found. No HIV has been contracted from IVF in 21 years as far as anyone knows.
2. Quarantining embryos will significantly increase costs and will increase the numbers of cycles needed to obtain the same pregnancy rate. (If you can estimate what that increased cost would be at your institute, please do so.)
3. Quarantining embryos will decrease the success rate for donor IVF. (If you can estimate the approximate decrease at your institute, please do so. The national average is about half).
4. There will be unnecessary deaths of embryos from the proposed rules to mandate freezing. (We estimate that possibly 9,000 embryos will be lost per year, representing a terrible loss of biological material and potential human lives.)
5. Increased delay causes anxiety and possible increased health risk in the woman delaying childbirth.

Summary: The FDA is interfering with the practice of medicine by attempting to require the quarantining of embryos resulting from donor egg IVF. There is no scientific justification (any transmission of HIV or other infectious disease) from IVF. Quarantining would increase costs, decrease success rate (pregnancy rate), and cause the unnecessary death of embryos and a delay in childbirth in an already older patient.

Finally, in the proposed rules, there seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk (so far no risk) associated with the use of isolated and washed sperm cells, oocytes and embryos.

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